

09937875.100102

533 Rec'd PCT/PTO 01 OCT 2001

FORM PTO-1390 REV. 5-93 <b>TRANSMITTAL LETTER TO THE UNITED STATES          DESIGNATED/ELECTED OFFICE (DO/EO/US)          CONCERNING A FILING UNDER 35 U.S.C. 371</b>		US DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE ATTORNEYS DOCKET NUMBER <b>P01,0337</b>
		U.S. APPLICATION NO. (if known, see 37 CFR 1.5) <b>09/937875</b>
INTERNATIONAL APPLICATION NO. <b>PCT/SE00/00572</b>	INTERNATIONAL FILING DATE <b>23 March 2000</b>	PRIORITY DATE CLAIMED <b>31 March 1999</b>
TITLE OF INVENTION <p style="text-align: center;"><b>A RATE ADAPTIVE PACEMAKER</b></p>		
APPLICANT(S) FOR DO/EO/US <p style="text-align: center;"><b>MART MIN, ANDRES KINK and TOOMAS PARVE</b></p>		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: <ol style="list-style-type: none"> <li>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</li> <li>3. <input checked="" type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay.</li> <li>4. <input checked="" type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.</li> <li>5. <input checked="" type="checkbox"/> A copy of International Application as filed (35 U.S.C. 371(c)(2)) - drawings attached.             <ol style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau).</li> <li>b. <input type="checkbox"/> has been transmitted by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US)</li> </ol> </li> <li>6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2) -</li> <li>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau).</li> <li>b. <input type="checkbox"/> have been transmitted by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ol> </li> <li>8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</li> <li>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</li> <li>10. <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</li> </ol> <p>Items 11. to 16. below concern other document(s) or information included:</p> <li>11. <input type="checkbox"/> An Information Disclosure Statement under 37 C.F.R. 1.97 and 1.98; (PTO 1449, Prior Art, Search Report).</li> <li>12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 C.F.R. 3.28 and 3.31 is included.          (Separate envelope)</li> <li>13. <input type="checkbox"/> A FIRST preliminary amendment.  <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.</li> <li>14. <input type="checkbox"/> A substitute specification, including red-lined version</li> <li>15. <input type="checkbox"/> A change of power of attorney and/or address letter.</li> <li>16. <input checked="" type="checkbox"/> Other items or information:             <ol style="list-style-type: none"> <li>a. <input type="checkbox"/> Request for Approval of Drawing Changes</li> <li>B <input checked="" type="checkbox"/> Express Mail Label EL 843741752US</li> </ol> </li>		

410 Rec'd PCT/PTO 01 OCT 2001

U.S. APPLICATION NO. (if known, see 37 C.F.R. 1.5) <b>09/937875</b>		INTERNATIONAL APPLICATION NO. PCT/SE00/00572		ATTORNEY'S DOCKET NUMBER P01.0337	
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17. <input checked="" type="checkbox"/> The following fees are submitted:  <b>BASIC NATIONAL FEE (37 C.F.R. 1.492(a)(1)-(5):</b> Search Report has been prepared by the EPO or JPO ..... \$890.00  International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) \$710.00  No international preliminary examination fee paid to USPTO (37 C.F.R. 1.482) but international search fee paid to USPTO (37 C.F.R. 1.445(a)(2)) ..... \$740.00  Neither international preliminary examination fee (37 C.F.R. 1.482) nor international search fee (37 C.F.R. 1.445(a)(2)) paid to USPTO ..... \$1040.00  International preliminary examination fee paid to USPTO (37 C.F.R. 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) ..... \$100.00  <div style="text-align: right;"><b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b></div>				CALCULATIONS		PTO USE ONLY																																																																															
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 C.F.R. 1.492(e)).  <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 20%;">Claims</th> <th style="width: 20%;">Number Filed</th> <th style="width: 20%;">Number Extra</th> <th style="width: 20%;">Rate</th> <th style="width: 20%;"></th> <th style="width: 20%;"></th> </tr> <tr> <td>Total Claims</td> <td>13 - 20 =</td> <td>0</td> <td>X \$18.00</td> <td>\$</td> <td></td> </tr> <tr> <td>Independent Claims</td> <td>1 - 3 =</td> <td>0</td> <td>X \$84.00</td> <td>\$</td> <td></td> </tr> <tr> <td colspan="3">Multiple Dependent Claims</td> <td>\$280.00 +</td> <td>\$280.00</td> <td></td> </tr> <tr> <td colspan="4" style="text-align: right;"><b>TOTAL OF ABOVE CALCULATIONS =</b></td> <td>\$1170.00</td> <td></td> </tr> <tr> <td colspan="4">Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 C.F.R. 1.9, 1.27, 1.28)</td> <td>\$</td> <td></td> </tr> <tr> <td colspan="4" style="text-align: right;"><b>SUBTOTAL =</b></td> <td>\$1170.00</td> <td></td> </tr> <tr> <td colspan="4">Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).</td> <td>\$</td> <td></td> </tr> <tr> <td colspan="4" style="text-align: right;"><b>TOTAL NATIONAL FEE =</b></td> <td>1170.00</td> <td></td> </tr> <tr> <td colspan="4">Fee for recording the enclosed assignment (37 C.F.R. 1.21(h). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property +</td> <td></td> <td></td> </tr> <tr> <td colspan="4" style="text-align: right;"><b>TOTAL FEES ENCLOSED =</b></td> <td>\$1170.00</td> <td></td> </tr> <tr> <td colspan="4"></td> <td style="text-align: center;">Amount to be refunded</td> <td style="text-align: center;">\$</td> </tr> <tr> <td colspan="4"></td> <td style="text-align: center;">charged</td> <td style="text-align: center;">\$</td> </tr> </table>				Claims	Number Filed	Number Extra	Rate			Total Claims	13 - 20 =	0	X \$18.00	\$		Independent Claims	1 - 3 =	0	X \$84.00	\$		Multiple Dependent Claims			\$280.00 +	\$280.00		<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$1170.00		Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 C.F.R. 1.9, 1.27, 1.28)				\$		<b>SUBTOTAL =</b>				\$1170.00		Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$		<b>TOTAL NATIONAL FEE =</b>				1170.00		Fee for recording the enclosed assignment (37 C.F.R. 1.21(h). The assignment must be accompanied by an appropriate cover sheet (37 C.F.R. 3.28, 3.31). \$40.00 per property +						<b>TOTAL FEES ENCLOSED =</b>				\$1170.00						Amount to be refunded	\$					charged	\$				
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a. ☒ A check in the amount of \$1170.00 to cover the above fees is enclosed.

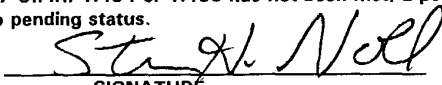
b. ☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 501519. A duplicate copy of this sheet is enclosed.

**NOTE:** Where an appropriate time limit under 37 C.F.R. 1.494 or 1.495 has not been met, a petition to revive (37 C.F.R. 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

**SEND ALL CORRESPONDENCE TO:**

**Schiff Hardin & Waite**  
 Patent Department  
 6600 Sears Tower  
 Chicago, Illinois 60606  
 Customer No. 26574

  
 SIGNATURE  
 \_\_\_\_\_  
 Steven H. Noll  
 NAME  
 \_\_\_\_\_  
 28,982 (Registration No.)

BOX PCT

IN THE UNITED STATES DESIGNATED OFFICE  
OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
UNDER THE PATENT COOPERATION TREATY-CHAPTER II

5      **AMENDMENT "A" PRIOR TO ACTION AND SUBMISSION OF**  
                                 **SUBSTITUTE SPECIFICATION**

APPLICANTS:      Min et al.

SERIAL NO.:      09/937,875

FILED:      October 1, 2001

10      TITLE:      "A RATE ADAPTIVE PACEMAKER"

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

Applicants herewith amend the above-referenced PCT application as  
15 follows, and requests entry of the Amendment prior to examination in the  
United States National Examination Phase.

**IN THE SPECIFICATION:**

20      Please enter the substitute specification submitted herewith pursuant  
to 37 C.F.R. §1.125(b). The substitute specification is based on amended  
sheets 1, 2 and 3, filed during earlier PCT prosecution, and original sheets  
4, 5 and 6. A marked-up copy showing all of changes made in the substitute  
specification is also submitted herewith. The substitute specification does  
not contain any new matter.

25      **IN THE DRAWINGS:**

Please amend each of Figures 1 and 2 as shown on the drawing copy  
marked in red attached to the Request for Approval of Drawing Changes,  
filed simultaneously herewith.

**IN THE CLAIMS:**

On amended sheet 7, in line 1, cancel "*Claims*" and substitute:  
--WE CLAIM AS OUR INVENTION-- therefor.

5 Cancel claims 1-6 on substitute sheets 7 and 8, and substitute the following claims therefor:

--7. A rate adaptive pacemaker comprising:  
an arrangement adapted for interaction with a subject for obtaining an  
electrical signal representing cardiac demand of said subject;  
a computing unit supplied with said signal for calculating an actual  
10 cardiac output CO, and a cardiac output CO<sub>rest</sub> for said subject  
at rest;  
a pacing rate controller also supplied with said signal for generating,  
as an output, a pacing rate dependent on said cardiac  
demand; and  
15 a pacing rate limiter connected to said computing unit and to said  
pacing rate controller for downwardly limiting said pacing rate,  
said pacing rate limiter calculating a stroke volume SV and a  
stroke volume SV<sub>rest</sub> for said subject at rest, and downwardly  
limiting said pacing rate so that a first predetermined relation  
20 CO > CO<sub>rest</sub> and a second predetermined relation SV/SV<sub>rest</sub> <  
L are satisfied, wherein L is a predetermined constant in a  
range between 1.2 and 1.5.

8. A rate adaptive pacemaker as claimed in claim 7 wherein said  
pacing rate limiter comprises a lower limit setting unit for setting a lower limit  
25 value for said pacing rate and a lower limit determining unit wherein SV and  
SV<sub>rest</sub> are determined, and wherein a relation between CO and CO<sub>rest</sub> and a  
relation between SV and SV<sub>rest</sub> are determined, and for calculating a lower  
pacing rate limit value from said relations for supply to said limit setting unit.

-3-

9. A rate adaptive pacemaker as claimed in claim 8 wherein said lower limit determining unit includes a comparator for comparing  $SV/SV_{rest}$  to L to ensure that  $(SV/SV_{rest} < L)$  is satisfied, and for calculating said lower pacing rate limit value as a product of  $HR_{rest}$  and  $Sv_{rest}/SV$ , wherein  $HR_{rest}$  is a heart rate for said subject at rest, provided  $(SV/SV_{rest}) < L$  is satisfied.

10. A rate adaptive pacemaker as claimed in claim 7 wherein said arrangement for determining cardiac demand comprises a bioimpedance measuring unit adapted to measure a cardiac bioimpedance as a function of time as said signal representing cardiac demand.

11. A rate adaptive pacemaker as claimed in claim 7 wherein said arrangement for determining cardiac demand comprises an ECG measuring unit for generating an ECG signal as said signal representing cardiac demand.

12. A rate adaptive pacemaker as claimed in claim 7 wherein said arrangement for determining cardiac demand is a dynamic distance measuring unit which generates a distance signal as said signal representing cardiac demand.--

#### **IN THE ABSTRACT:**

Please add the Abstract as set forth on separately numbered page 7, attached hereto.

#### **REMARKS:**

The present Amendment makes changes editorial changes in the specification, drawings and claims, and adds an Abstract, to conform the present PCT application to the requirements of United States patent practice.

No departure in the claim language of claims 7-12 presented herein, as

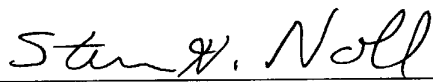
-4-

compared to original claims 1-6, has been made for the purpose of distinguishing any of claims 7-12 over the teachings of the prior art of record. Claims 7-12 are considered to have the same scope as original claims 1-6, and accordingly no difference in the claim language between those sets of  
5 claims is intended by the Applicants as a surrender of any of the subject matter encompassed within the scope of original claims 1-6.

Early consideration of the present PCT application is respectfully requested.

Submitted by,

10

 (Reg. 28,982)

SCHIFF, HARDIN & WAITE

**CUSTOMER NO. 26574**

Patent Department

6600 Sears Tower

15

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Chicago, Illinois 60606

Telephone: 312/258-5790

Attorneys for Applicants.

BOX PCT  
IN THE UNITED STATES DESIGNATED OFFICE  
OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
UNDER THE PATENT COOPERATION TREATY-CHAPTER II

5           **REQUEST FOR APPROVAL OF DRAWING CHANGES**

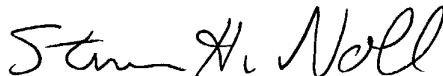
APPLICANTS:       Min et al.  
SERIAL NO.:        09/937,875  
FILED:             October 1, 2001  
TITLE:             "A RATE ADAPTIVE PACEMAKER"

10   Assistant Commissioner for Patents,  
      Washington, D.C.

S I R:

      Applicants herewith request approval of the drawing changes in each  
of Figures 1 and 2, as shown on the drawing copy marked in red attached  
15   hereto.

Submitted by,



(Reg. 28,982)

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Telephone: 312/258-5790  
Attorneys for Applicants.

20

25

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the  
United States Postal Service as First Class Mail in an envelope addressed  
to: Assistant Commissioner for Patents, United States Patent and Trademark  
Office, P.O. Box 2327, Arlington, Virginia 22202 on Jan. 18, 2002

30



STEVEN H. NOLL

Fig. 1

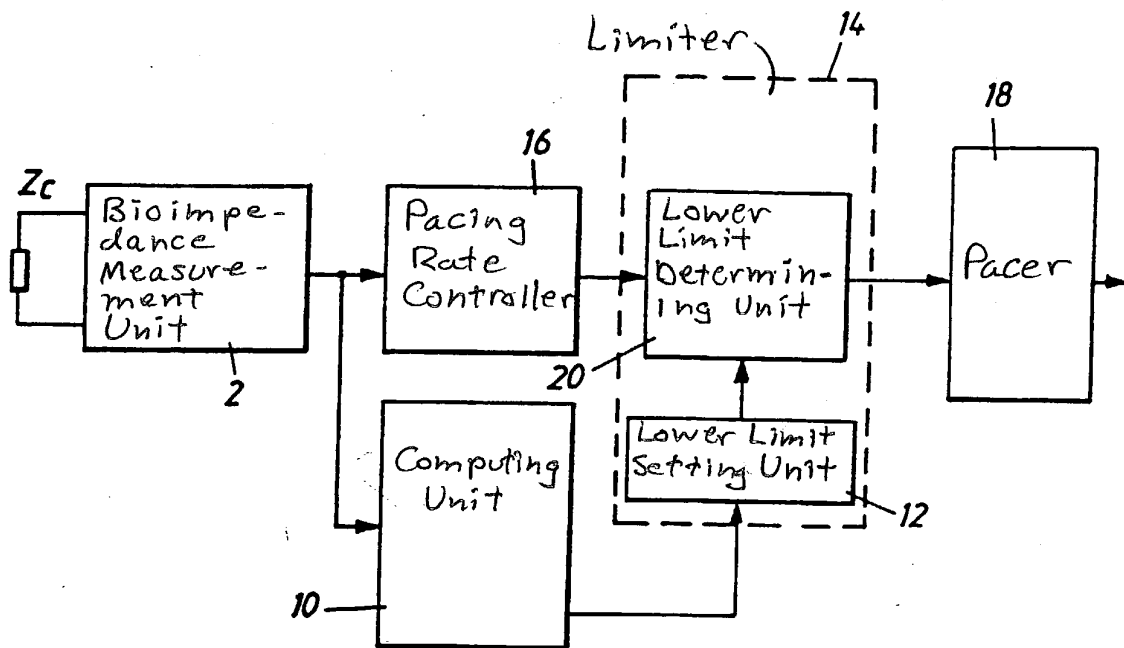
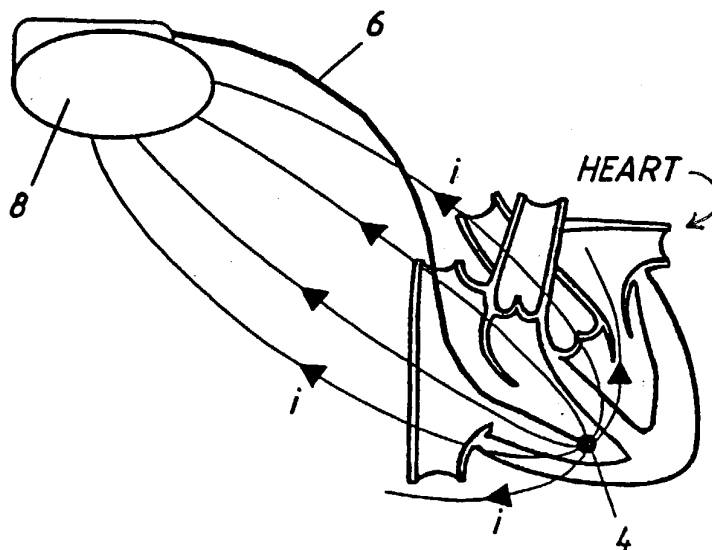


Fig. 2





**SUBSTITUTE SPECIFICATION**

**SPECIFICATION**

**TITLE**

**"A RATE ADAPTIVE PACEMAKER"**

**BACKGROUND OF THE INVENTION**

5 **Field of the Invention**

The present invention relates to a rate adaptive pacemaker of the type having an arrangement for determining the demand of the patient's organism, a pacing rate control for controlling the pacing rate in response to the patient's demand, and a pacing rate limiter for preventing the pacing rate  
10 from becoming too low.

**Description of the Prior Art.**

The pacing rate of a rate adaptive pacemaker may become too low due to the physical demand of the patient's organism and heart. This may result in lack of oxygen supply to the myocardium. Under certain conditions  
15 the heart may not be able to fulfil the physiological needs of the patient's organism and heart if the pacing rate is not limited.

It is known to set a lower limit for the pacing rate. This limit value is normally determined from the patient's diagnosis and a constant or externally programmable limit can be set. Thus United States Patent No.  
20 4,535,774 describes a stroke volume controlled pacemaker, in which the heart rate is permitted to range between prescribed minimum and maximum heart rate values. Further, in United States Patent No. 5,861,011 a pacemaker is disclosed having a system for determining the circadian rhythm by examining variations in the QT interval and adjusting the pacemaker night

-2- **SUBSTITUTE SPECIFICATION**

time setting of a lower rate limit to the lower value than the pacemaker daytime setting of the lower rate limit. In United States Patent No. 5,183,040, an antitachycardia pacer is disclosed which analyzes cardiac output information for assessing hemodynamic status and determining  
5 adequate blood supply.

Thus, a pacing rate that is too low may cause an influx of blood enriched with oxygen that also is too low. A prescribed suitable lower pacing rate limit avoids the slow influx of the fresh blood. At the same time this lower limit value should be low enough so as to not to disturb a peaceful  
10 sleep. In that case the patient can feel more healthy in various everyday life conditions including peaceful sleeping.

**SUMMARY OF THE INVENTION**

An object of the present invention is to provide a rate adaptive pacemaker in which the pacing rate is prevented from becoming too low,  
15 such that the above discussed inconveniences for the patient are avoided.

The above object is achieved in accordance with the principles of the present invention in a rate adaptive pacemaker having an arrangement adapted for interaction with a subject for obtaining an electrical signal representing cardiac demand of the subject, a computing unit supplied with  
20 the signal for calculating an actual cardiac output CO and a cardiac output  $CO_{rest}$  for the subject at rest, a pacing rate controller also supplied with the signal for generating, as an output, a pacing rate dependent on the cardiac demand, and a pacing rate limiter connected to the computing unit and to the

-3- **SUBSTITUTE SPECIFICATION**

5 pacing rate controller for downwardly limiting the pacing rate, wherein the  
pacing rate limiter calculates a stroke volume SV and a stroke volume  $SV_{rest}$   
for the subject at rest, and downwardly limits the pacing rate so that a first  
predetermined relation  $CO > CO_{rest}$  and a second predetermined relation  
5  $SV/SV_{rest} < L$  are satisfied, wherein L is a predetermined constant in a range  
between 1.2 and 1.5.

Thus, by satisfying two predetermined relations the pacemaker  
according to the invention ensures a sufficient minimum energy supply to the  
patient's organism or body and at the same time the maximum value of the  
10 stroke volume is limited and these conditions are continuously automatically  
checked.

In one embodiment of the pacemaker 20 according to the invention  
the first predetermined relation is

$$CO > CO_{rest} \quad (1)$$

15 and the second predetermined relation is

$$(SV)/(SV_{rest}) < L \quad (2)$$

where L denotes a predetermined constant  $> 1$ , preferably equal to a value  
between 1.2 and 1.5. In this way it is ensured that the actual cardiac output  
will not become lower than the rest state cardiac output  $CO_{rest}$  as well as  
20 ensuring that the actual stroke volume will be less than a maximum allowed  
value equal to  $L \times SV_{rest}$ , where L typically has a value between 1.2 and 1.5,  
depending on the health of the patient's myocardium. By satisfying both

-4- **SUBSTITUTE SPECIFICATION**

these conditions simultaneously a physiologically well founded heart work management at low work loads is ensured.

In another embodiment of the pacemaker according to the invention the pacing rate limiter includes a lower limit setting unit for setting a lower limit value for the pacing rate, and a lower limit determining unit for determining the relation between actual cardiac output (CO) and cardiac output (CO<sub>rest</sub>) for the patient in rest conditions, and the relation between actual stroke volume (SV) and a rest stroke volume (SV<sub>rest</sub>) and for calculating a lower pacing rate limit value from the relations for supply to said limit setting unit. The lower limit determining unit includes a stroke volume measuring unit for measuring actual stroke volume SV and a comparator for comparing measured actual stroke volume SV with stroke volume SV<sub>rest</sub> for the patient in rest conditions to ensure that the inequality

$$SV/SV_{rest} < L \quad (3)$$

is satisfied. The lower limit determining unit is adapted to calculate a lower pacing rate limit value from the equation

$$\text{lower pacing rate limit} = HR_{rest} (SV_{rest}/SV) \quad (4)$$

where HR<sub>rest</sub> denotes the heart rate for the patient in rest conditions, provided that said inequality is satisfied. In this way the lower pacing rate limit is continuously automatically calculated and it may also happen that the lower pacing rate limit becomes lower than the typical heart rate HR<sub>rest</sub> for rest conditions of the patient.

-5- **SUBSTITUTE SPECIFICATION**

In another embodiment of the pacemaker according to the invention a bioimpedance measurement unit is provided to measure the cardiac bioimpedance as a function of time for determining therefrom actual cardiac output CO and actual stroke volume SV from the measured cardiac bioimpedance. These parameters thus are obtained in an easy and reliable way from the time variation of the bioimpedance measured between a standard intracardiac electrode and the housing of the pacemaker, when an excitation current proceeds from the electrode tip.

**DESCRIPTION OF THE DRAWINGS**

Figure 1 is a schematic block diagram of a rate adaptive pacemaker constructed and operating in accordance with the principles of the present invention.

Figure 2 illustrates the principle of bioimpedance measurements between the tip of an intracardial electrode and the metallic housing of the pacemaker, these measurements being used in the rate adaptive pacemaker of Figure 1.

**DESCRIPTION OF THE PREFERRED EMBODIMENTS**

To avoid the current cardiac output CO

$$CO = SV \times HR \quad (5)$$

becomes lower than the rest state cardiac output  $CO_{rest}$  the pacing rate must be above a lower pacing rate limit given by

$$\text{lower pacing rate limit} = (CO_{rest})/(SV) \quad (6)$$

and since



-7- **SUBSTITUTE SPECIFICATION**

5,807,272. Thus the time variation of the intracardiac bioimpedance can be measured between the tip 4 of the intracardiac electrode 6 and the housing 8 of the pacemaker, when an excitation current is fed from the electrode tip 4, as schematically illustrated in Figure 2. Thus a standard pacing lead can  
5 be used for this measurement.

From the measured time variations  $AZ_c(t)$  the stroke volume SV needed for calculating the lower pacing rate limit according to equation (8) above, or for checking the inequalities (10) or (11), are determined in a computing unit 10, see Figure 1.

10 The calculated lower limit value is supplied to a lower limit 30 setting unit 12 of a pacing rate limiter 14.

A pacing rate controller 16 is also provided for controlling the pacing rate of the pacer or pulse generator 18 in response to the patient's demands. In a limiting unit 20 of the limiter 14 the demanded pacing rate is compared  
15 to the set lower limit pacing rate and the actual pacing rate is limited to the set lower limit value if the demanded pacing rate reaches this limit value. Thus in the pacemaker according to the invention a lower limit value for the pacing rate is continuously automatically determined and it is continuously automatically verified that the actual pacing rate does not exceed the present  
20 lower limit value.

Alternatively, the pacemaker can be modified to continuously monitor that the inequalities (10) or (11) above are satisfied.

-8- **SUBSTITUTE SPECIFICATION**

Above bioimpedance measurements are described for determining the stroke volume SV. This parameter can, however, also be determined by other techniques, like by ECG measurements, by ultrasound technique, by radiometric and optical techniques etc. Generally all dynamic distance and/or capacity measuring methods are applicable.

5

Although modifications and changes may be suggested by those skilled in the art, it is the intention of the inventors to embody within the patent warranted hereon all changes and modifications as reasonably and properly come within the scope of their contribution to the art.



99P2005P

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### Technical Field

The present invention relates to a rate adaptive pacemaker comprising a means for determining the demand of the patient's organism, a pacing rate controlling means for controlling the pacing rate in response to the patient's demand, and a pacing rate limiting means for preventing the pacing rate from becoming too low.

### 10 Background Art

The pacing rate of a rate adaptive pacemaker may become too low due to the physical demand of the patient's organism and heart. This may result in lack of oxygen supply to the myocardium. Under certain conditions the heart may not be able to fulfil the physiological needs of the patient's organism and heart if the pacing rate is not limited.

It is previously known to set a lower limit for the pacing rate. This limit value is normally determined from the patient's diagnosis and a constant or externally programmable limit can be set. Thus US-A-4,535,774 describes a stroke volume controlled pacemaker, in which the heart rate is permitted to range between prescribed minimum and maximum heart rate values. Further, in US-A-5,861,011 a pacemaker is disclosed having a system for determining the circadian rhythm by examining variations in the QT interval and adjusting the pacemaker night time setting of a lower rate limit to a lower value than the pacemaker daytime setting of the lower rate limit. In US-A-5,183,040, an antitachycardia pacer is disclosed which analyzes cardiac output information for assessing hemodynamic status and determining adequate blood supply.

Thus, too low a pacing rate may cause too slow influx of blood enriched with oxygen. A prescribed suitable lower pacing rate limit avoids the slow influx of the fresh blood. At the same time this lower limit value should be low enough

99P2005P

2

not to disturb a peaceful sleep. In that case the patient can feel more healthy in various everyday life conditions including peaceful sleeping.

- 5 The purpose of the present invention is to provide a rate adaptive pacemaker in which the pacing rate is prevented in a new way from becoming too low, such that the above discussed inconveniences for the patient are avoided.

10      Disclosure of the Invention

This purpose is obtained by a rate adaptive pacemaker according to claim 1.

15 Thus, by satisfying two predetermined relations the pacemaker according to the invention ensures a sufficient minimum energy supply to the patient's organism or body and at the same time the maximum value of the stroke volume is limited and these conditions are continuously automatically checked, and where the first predetermined relation is

$$20 \quad CO > CO_{rest} \quad (1)$$

and said second predetermined relation is

$$(SV) / (SV_{\text{rest}}) < L \quad (2)$$

where  $L$  denotes a predetermined constant equal to a value between 1.2 and 1.5. In this way the actual cardiac output is ensured not to become lower than the rest state cardiac output  $CO_{rest}$  and the actual stroke volume is ensured to be less than a maximum allowed value equal to  $L \times SV_{rest}$ , where  $L$  typically has a value between 1.2 and 1.5, depending on the health of the patient's myocardium. By satisfying both these conditions simultaneously a physiologically well founded heart work management at low work loads is ensured.

Preferred embodiments are set forth in the dependent claims.

99P2005P

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According to advantageous embodiments of the pacemaker according to the invention the pacing rate limiting means includes a lower limit setting means for setting a lower limit value for the pacing rate, and a lower limit determining means for determining the relation between actual cardiac output (CO) and cardiac output ( $CO_{rest}$ ) for the patient in rest conditions, and the relation between actual stroke volume (SV) and a rest stroke volume ( $SV_{rest}$ ) and calculating a lower pacing rate limit value from said relations for supply to said limit setting means, and said lower limit determining means includes a stroke volume measuring means for measuring actual stroke volume SV and comparison means for comparing measured actual stroke volume SV with stroke volume  $SV_{rest}$  for the patient in rest conditions to ensure that the inequality

$$SV/SV_{rest} < L \quad (3)$$

is satisfied and said lower limit determining means is adapted to calculate a lower pacing rate limit value from the equation

$$\text{lower pacing rate limit} = HR_{rest} \cdot (SV_{rest}/SV) \quad (4)$$

where  $HR_{rest}$  denotes the heart rate for the patient in rest conditions, provided that said inequality is satisfied. In this way the lower pacing rate limit is continuously automatically calculated and it may also happen that the lower pacing rate limit becomes lower than the typical heart rate  $HR_{rest}$  for rest conditions of the patient.

According to another advantageous embodiment of the pacemaker according to the invention a bioimpedance measurement unit is provided to measure the cardiac bioimpedance as a function of time for determining therefrom actual cardiac output CO and actual stroke volume SV from the measured cardiac bioimpedance. In this way these parameters are obtained in an easy and reliable way from the time variation of the bioimpedance measured between a standard intracardiac

$$30 \quad SV/SV_{\text{rest}} < L \quad (11)$$

A pacing rate controller 16 is also provided for controlling the pacing rate of the pacer or pulse generator 18 in response to the patient's demands. In a limiting unit 20 of the limiter 14 the demanded pacing rate is compared to the set lower limit pacing rate and the actual pacing rate is limited to the set lower limit value if the demanded pacing

rate reaches this limit value. Thus in the pacemaker according to the invention a lower limit value for the pacing rate is continuously automatically determined and it is continuously automatically verified that the actual pacing  
5 rate does not exceed the present lower limit value.

Alternatively, the pacemaker can be modified to continuously monitor that the inequalities (10) or (11) above are  
10 satisfied.

10

Above bioimpedance measurements are described for determining the stroke volume SV. This parameter can, however, also be determined by other techniques, like by ECG measurements, by ultrasound technique, by radiometric and optical techniques  
15 etc. Generally all dynamic distance and/or capacity measuring methods are applicable.

99P2005P

7

*Claims*

1. A rate adaptive pacemaker comprising a means (2) for  
determining the demand of the patient's organism, a pacing  
5 rate controlling means (16) for controlling the pacing rate  
in response to the patient's demand, and a pacing rate  
limiting means (14) for preventing the pacing rate from  
becoming too low, said pacing rate limiting means (14) being  
adapted to limit the pacing rate downwards such that a first  
10 predetermined relation is satisfied between actual cardiac  
output (CO) and cardiac output (CO<sub>rest</sub>) for the patient in  
rest conditions and a second predetermined relation is  
satisfied between actual stroke volume (SV) and rest stroke  
volume (SV<sub>rest</sub>), **characterized in** that said first  
15 predetermined relation is

$$CO > CO_{rest}$$

and said second predetermined relation is

$$(SV)/(SV_{rest}) < L$$

where L denotes a predetermined constant equal to a value  
20 between 1.2 and 1.5.

2. The pacemaker according to claim 1, **characterized in**  
that said pacing rate limiting means (14) includes a lower  
limit setting means for setting a lower limit value for the  
25 pacing rate, and a lower limit determining means (10) for  
determining the relation between actual cardiac output (CO)  
and cardiac output (CO<sub>rest</sub>) for the patient in rest conditions  
and the relation between actual stroke volume (SV) and a rest  
stroke volume (SV<sub>rest</sub>) and calculating a lower pacing rate  
30 limit value from said relations for supply to said limit  
setting means.

3. The pacemaker according to claim 2, **characterized in**  
that said lower limit determining means (10) includes a  
35 stroke volume measuring means for measuring actual stroke  
volume SV and comparison means for comparing measured actual

99P2005P

8

stroke volume SV with stroke volume  $SV_{rest}$  for the patient in rest conditions to ensure that the inequality

$$SV/SV_{rest} < L$$

5 is satisfied, and in that said lower limit determining means (10) is adapted to calculate a lower pacing rate limit value from the equation

$$\text{lower pacing rate limit} = HR_{rest} \cdot (SV_{rest}/SV)$$

10

where  $HR_{rest}$  denotes the heart rate for the patient in rest conditions, provided that said inequality is satisfied.

15

4. The pacemaker according to any of the claims 1-3, **characterized in** that a bioimpedance measurement unit (2) is provided to measure the cardiac bioimpedance as a function of time for determining therefrom actual cardiac output (CO) and actual stroke volume (SV) from the measured cardiac bioimpedance.

20

5. The pacemaker according to any of the claims 1-3, **characterized in** that an ECG measuring and analyzing unit is provided to measure ECG and determine therefrom actual cardiac output (CO) and actual stroke volume (SV).

25

6. The pacemaker according to any one of claims 1-4, **characterized in that** a dynamic distance measuring and analyzing unit is provided to determine therefrom actual cardiac output (CO) and actual stroke volume (SV).

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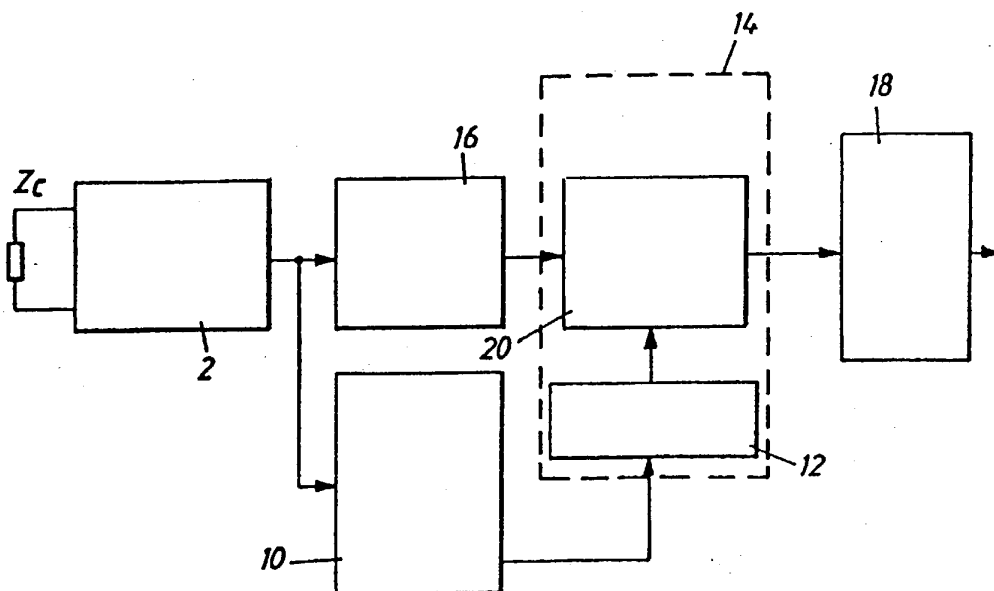
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(54) Title: A RATE ADAPTIVE PACEMAKER



(57) Abstract

A rate adaptive pacemaker comprises a means (2) for determining the demand of the patient's organism, a pacing rate controlling means (16) for controlling the pacing rate in response to the patient's demand, and a pacing rate limiting means (20) for preventing the pacing rate from becoming too low. The pacing rate limiting means is adapted to limit the pacing rate downwards such that a first predetermined relation is satisfied between actual cardiac output (CO) and cardiac output (CO<sub>rest</sub>) for the patient in rest conditions and a second predetermined relation is satisfied between actual stroke volume (SV) and rest stroke volume (SV<sub>rest</sub>).

Fig. 1

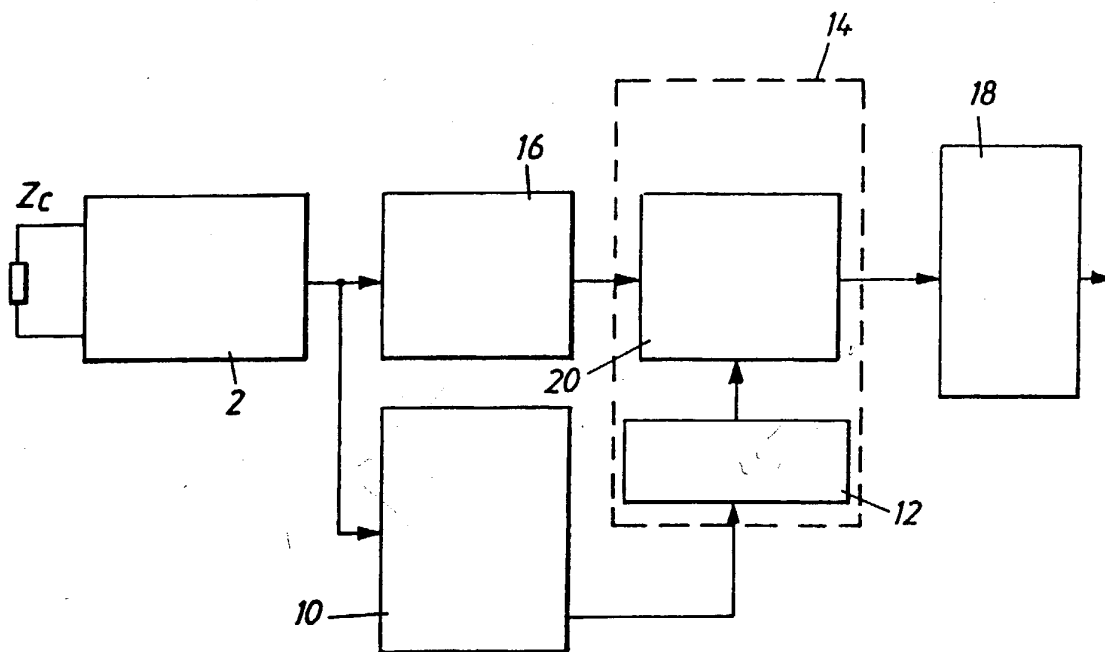
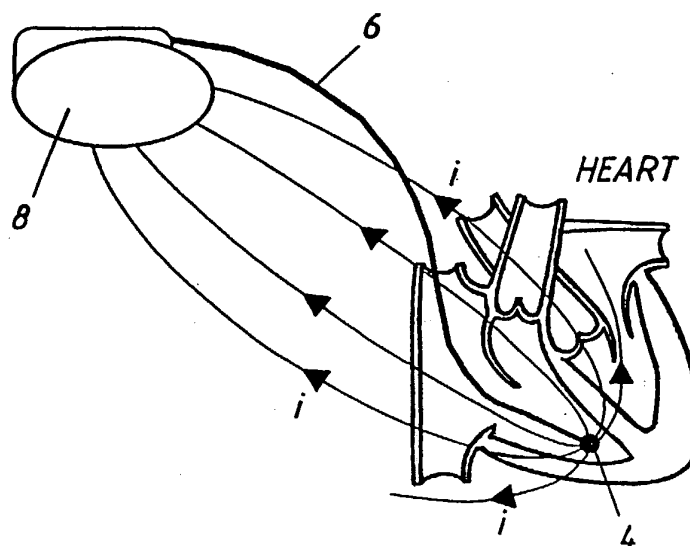


Fig. 2



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 My residence, post office address and citizenship are as stated below next to my name.  
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the specification of which (check only one item below):

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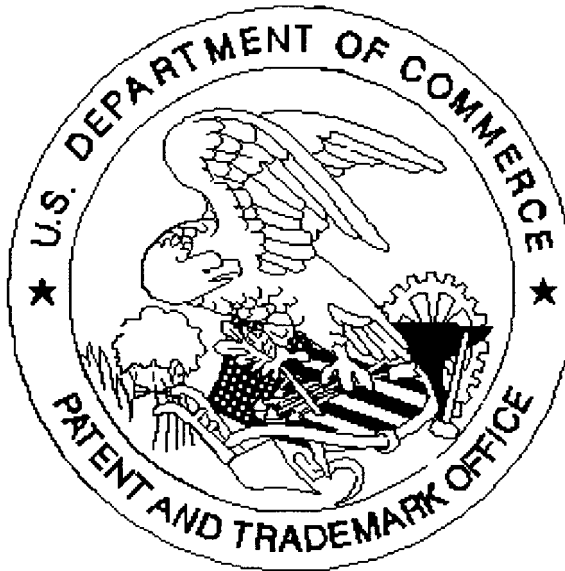
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